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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,882	01/18/2002	Steven M. Ruben	PZ038P1CI	6523

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EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,882	RUBEN ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9, 10, 14, and 21; drawn to nucleic acids and compositions containing same, classified in Class 536, subclass 23.1 and Class 435, subclasses 243, 320.1, and 325. If this Group is elected, then the below sequence election requirement also is required.

II. Claim 8; drawn to a method of making a recombinant host cell comprising a nucleic acid, classified in Class 435, subclass 440. If this Group is elected, then the below sequence election requirement also is required

III. Claims 11, 12, 16, and 23; drawn to polypeptides and compositions containing same, classified in Class 530, subclasses 300 and 350. If this Group is elected, then the below sequence election requirement also is required.

IV. Claim 13; drawn to an antibody specifically recognizing a polypeptide, classified in Class 530, subclass 387.1. If this Group is elected, then the below sequence election requirement also is required.

V. Claim 15; drawn to methods of making an isolated polypeptide via culturing a recombinant host cell; classified in Class 435, subclass 69.1. If this Group is elected, then the below sequence election requirement also is required.

VI. Claim 17; drawn to methods of preventing, treating, or ameliorating a medical condition utilizing a polypeptide or polynucleotide, classified in Class 514, subclasses 2 or 44. If this Group is elected then the below sequence election requirement is also required.

VII. Claim 18; drawn to methods of diagnosing a pathological condition via determining the presence or absence of a mutation in a polynucleotide, classified in Class 435, subclass 6. If this Group is elected then the below sequence election requirement is also required.

VIII. Claim 19; drawn to methods of diagnosing a pathological condition via determining the presence or amount of expression of a polypeptide, classified in Class 435, subclass 7.1. If this Group is elected then the below sequence election requirement is also required.

IX. Claims 20 and 23; drawn to methods for identifying a binding partner to a polypeptide and the product so produced, classified in Class 435, subclass 7.1. If this Group is elected then the below sequence election requirement is also required.

X. Claim 22; drawn to methods for identifying a protein activity in the supernatant of a cell which expresses a polynucleotide, classified in Class 435, subclass 4. If this Group is elected then the below sequence election requirement is also required.

SEQUENCE ELECTION REQUIREMENT APPLICABLE TO ALL GROUPS:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to polypeptide sequences, the Applicants must further elect a single polypeptide sequence. For an elected Group drawn to polynucleotide

sequences, the Applicants must elect a single polynucleotide sequence. It is noted that a Group drawn to polynucleotides may be defined by an elected polypeptide sequence. It is also noted that a Group drawn to polypeptide or polynucleotide sequence may also be defined by the corresponding ATCC Deposit Number. For an elected Group drawn to an antibody which recognizes a polypeptide, a single recognized polypeptide, albeit potentially defined by either a polynucleotide sequence, polypeptide sequence, or ATCC Number; must be elected. For the purposes of this election requirement, the election must be directed to what specific sequence defines the embodiments being examined, that is, polynucleotide sequence, polypeptide sequence, or ATCC Number (polynucleotide therein or polypeptide expressed thereby). A combination of any two or three of these will be deemed non-responsive to this election requirement. (See MPEP 803.04). The type of sequence elected will determine the embodiments examined, if Group VI above is elected. It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one polynucleotide sequence is elected, thus making the previous waiver for up to 10 elected polynucleotide sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences, instantly cited as polynucleotides, encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent

evidence to the contrary, each such polynucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. Polypeptides and antibodies recognizing such polypeptides are equivalently structurally distinct chemical compounds and are unrelated to one another. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

DISTINCTNESS BASIS BETWEEN INVENTIONS:

The distinctness basis between species has been summarized above.

The invention Groups are distinct, each from the other because of the following reasons:

The inventions of Groups [III, VI (polypeptide specie), VIII, and IX]; Groups [I, II, V, VI (polynucleotide specie), VII, and X]; and Group [IV (antibody)] are distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups III, VI (polypeptide specie), VIII, and IX; the critical feature is a polypeptide; for Groups I, II, V, VI (polynucleotide specie), VII, and X; the critical feature is a polynucleotide; and for Groups IV the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups III, VI (polypeptide specie), VIII, or IX to be directed as to its synthesis by a polynucleotide of Groups I, II, V, VI (polynucleotide specie), VII, or X; or recognized by an antibody of Groups IV, however, the completely separate chemical types of the inventions of the

polypeptide, polynucleotide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polypeptides, polynucleotides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of [III, VI (polypeptide specie), VIII, and IX]; [I, II, V, VI (polynucleotide specie), VII, and X] and [IV] are distinct invention types for restriction purposes.

The inventions of Groups III, VI (polypeptide specie), VIII, and IX are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group III can be used in the distinct processes of the inventions of Groups VI (polypeptide specie), VIII, and IX as well as the activity of a polypeptide can be utilized in an industrial process for chemical processing.

The inventions of Groups I, II, V, VI (polynucleotide specie), VII, and X are related as product and distinct process of use. The inventions can be shown to

be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polynucleotides of Group I can be used in the distinct processes of the inventions of Group II, V, VI (polynucleotide specie), VII, or X, or, alternatively, methods directed to screening via polynucleotide binding reactions. Alternatively, the polynucleotides of Group I can be used in antisense therapy which is also a clearly distinct usage of such polynucleotides.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform

with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549.

March 17, 2004

Ardin H. Marschel 3/17/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER